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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/839,779	04/20/2001	Amin I. Kassis	U0381-00001	2010
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EXAMINER

WEBER, JON P

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 01/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,779

Applicant(s)

KASSIS ET AL.

Examiner

Jon P Weber, Ph.D.

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 November 2003 has been entered.

Claims 5-22 have been presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Attorney was called on 31 December 2003 to set up a telephonic interview as requested in the response of 10 November 2003. No telephone reply has been received to date. This action will proceed in the absence of the requested interview since the deadline for the examiner to act on the response is due to expire.

Election/Restrictions

This application contains claims 4 and 22 drawn to an invention nonelected with traverse in Paper filed 26 November 2002. A complete reply to the final rejection **must** include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01, for the response to be complete. These claims were not canceled in the filing of the RCE although they should have been.

Claim Rejections - 35 USC § 102 and 103

Claims 1, 5-15 and 17-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hansen (US 5,851,527) and claims 1, 5-15 and 20 stand rejected under 35 U.S.C. 102(e) as being anticipated by Griffiths et al. (US 6,361,774).

Claims 1-3 and 5-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen (US 5,851,527) in view of Senter et al. (US 4,975,278), Shepard (US 6,495,553) and further in view of Camden (US 6,265,427), Griffin et al. (US 6,156,739) and Horwitz et al. (US 5,854,968).

It is argued that the instant claims require that the drug is water-insoluble. It is urged that the deposited free drug in Hansen and the less soluble drug of Griffiths are not the synonymous with precipitated or insoluble as instantly claimed.

It is well established in chemistry that the term insoluble is a relative one and only has meaning in terms of an equilibrium amount of a substance distributed between the solid precipitate and the solution surrounding it. This is taught extensively in terms of inorganic materials in most introductory courses of chemistry. The equilibrium constant for inorganic salts is referred to as K_{sp} and the extent to which the substance is dissolved in the solvent is the solubility. The smaller the value of the K_{sp} , the more insoluble the substance is. The metathesis reaction describes the replacement of a more soluble salt with a less soluble salt.

In the instant case, applicants argue the meaning of precipitate and insoluble, but without defining the terms with the precision of an actual equilibrium constant. Thus one is faced with the semantics of what is meant by the use of "deposited", "less soluble", "poorly soluble" and "precipitate" by the various authors of the instant application and the relied upon references.

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The position of the Office, absent a clear definition of terms in any of these references is to give the terms their broadest reasonable interpretation. That is, Hansen's depositing the free drug on a surface is equivalent to precipitating it from solution. The free drug must be sufficiently insoluble for a solid to form. Hence, it is not only a precipitate in the broadest meaning, but it is clearly insoluble as well. The use of "less soluble" and "poorly soluble" by Griffiths is interpreted in view of the teachings therein that they are following the teachings of Hansen 08/445,110 (now US 5,851,527 and cited herein as well). Thus, they must have the same meaning for these terms as Hansen. Further, it is known in the art of chemistry when discussing solubility of solids, that "less soluble" and "poorly soluble" terms are used to describe substances that are at least somewhat insoluble.

Applicant's arguments filed 10 November 2003 have been fully considered but they are not persuasive. The rejection under 35 U.S.C. 102 and 103 are adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114.

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See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

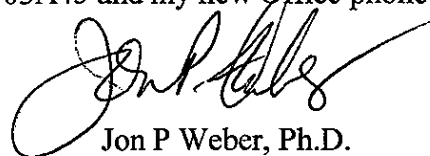
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

My new Office room number will be Rem-03A45 and my new Office phone number will be 571-272-0925 after 15 January 2004.



Jon P Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
7 January 2004